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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/500,159

11/09/2004

Giuseppe Passoni

2503-1104

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466 7590 09/28/2007
YOUNG & THOMPSON
745 SOUTH 23RD STREET
2ND FLOOR
ARLINGTON, VA 22202

EXAMINER

MAEWALL, SNIGDHA

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

09/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,159

Applicant(s)

PASSONI ET AL.

Examiner

Snigdha Maewall

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>06/25/2004</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Summary

1. Receipt of IDS filed on 06/25/2004 is acknowledged.

Claims included in the prosecution are **1-14**.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "optionally". It is not clear as to whether the limitation is really the limitation. Appropriate correction is required. Claim 2 recites the limitation "polycarboxylic acids and "long- chain acids". The metes and bounds of the claim are not defined and the claim is therefore indefinite.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Assmus et al. (US Patent No. 5,993,849) in view of Roversi et al. (WO 01/54674 A1) and further in view of Anderson et al. (US PG PUB 2002/0156188 A1).

Assmus et al. discloses an adhesive and binder for dermal and transdermal delivery systems. The polymers disclosed are structural acrylate or methacrylate monomers such as c1-c4 alkyl esters of acrylic or methacrylic acid. Dimethylaminoethyl methacrylate is particularly preferred as a monomer with functional tertiary amino groups (see column 3, lines 13-15 and lines 27-30). The copolymers can be formed by radical solution, bead or emulsion polymerization and can be in the form of extruded granulate, ground powder, solution or dispersion (see column 3, lines 57-59). Succinic acid and glutaric and oxalic acids are disclosed in column 3, lines 63-65 and plasticizers used in the disclosure are glycerin esters, citric acid alkyl esters, sebacic acid alkyl esters and polyethylene glycols etc. (see column 4, lines 17-18). The other additives included in the disclosure are stabilizers, pigments, antioxidants, wetting agents, pore

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formation agents and complexing agents etc. Polymer solutions or dispersions are mixed with additives so that the latter dissolves or are suspended (see column 5, lines 13-15). Adhesive layers that fix the system in place on the skin are particularly well tolerated because of their hydrophilic nature and are obtained by spreading the material out on the flat carriers, for instance, films, woven, or non woven textiles. After coating, a slightly adhesive siliconized cover film is also added (see column 5, lines 25-35).

Various active agents utilized in the invention are disclosed in column 6, lines 15-44).

Diclophenac is one of the preferred active agents.

Assmus et al. do not disclose polyoxylhydrogenated castor oil.

Roversi et al. discloses a patch for local and transdermal administration of active ingredients containing an anionic or electron attracting groups. The polymers included in the disclosure are Eudragit E100 polymers, polyvinylpyrrolidone, plasticizer, backing layer and protective layer (see page 3, lines 1-10 and abstract). Plasticizing agent such as glycerin and triethyl citrate are disclosed on page 4, lines 23-25. various drugs and polyhydroxylated castor oil is shown on page 5, lines 10-15 sodium diclofenac along with the claimed polymers are disclosed in example 2.

Roversi et al. do not disclose adhesive system of methacrylic acid and ester of acrylic acid. However, Anderson et al. discloses adhesive polymer of methacrylic acid and ester of acrylic acid and their uses as adhesive polymers (see paragraph [0027] and [0024].

It would have been obvious to the one of ordinary skilled in the art at the time the invention was made to incorporate polyoxylhydrogenated castor oil and adhesive

system in the composition forwarded by Assmus et al. because both castor oil and adhesive system help have been utilized successfully in the preparation of adhesive formulation. A skilled artisan would thus have been motivated to formulate an adhesive transdermal formulation by the combined teachings and suggestions provided by assmus et al., Roversi et al. and Anderson et al. with a reasonable expectation of success. With respect to the amount of the active agent applied per patch, it is the position of the examiner that such parameters can be optimized based on the amount of the active agent required.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

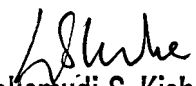
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Snigdha Maewall

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Gollamudi S. Kishore, PhD
Primary Examiner
Group 1800